**PCT** WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 10/00

A1

(11) International Publication Number: WO 00/45708

(43) International Publication Date: 10 August 2000 (10.08.00)

(21) International Application Number: PCT/US00/02086

(22) International Filing Date: 26 January 2000 (26.01.00)

(30) Priority Data:

| | | |
|---|---|---|
| 09/244,952 | 4 February 1999 (04.02.99) | US |
| 09/427,161 | 26 October 1999 (26.10.99) | US |

(71) Applicant: INTEG, INC. [US/US]; 2800 Patton Road, St. Paul, MN 55113 (US).

(72) Inventors: HILGERS, Michael, E.; 179 Grandview Avenue, Roseville, MN 55113 (US). SCHMIDT, Bruno, J.; 5344 St. Stevens Street, Moundsview, MN 55112 (US).

(74) Agent: BRUESS, Steven, C.; Merchant & Gould P.C., 3100 Northwest Center, 90 South Seventh Street, Minneapolis, MN 55402–4131 (US).

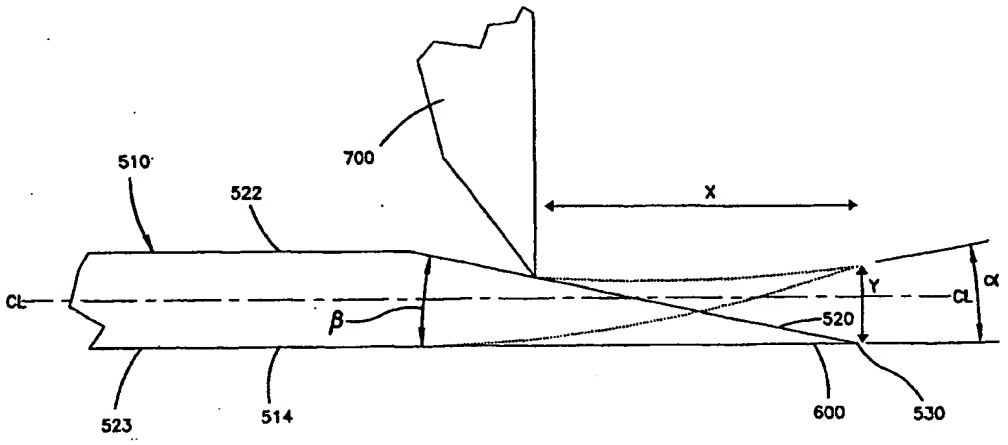
(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (Utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published**

*With international search report.*

*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: NEEDLE FOR BODY FLUID TESTER




(57) Abstract

An apparatus for collecting a body fluid for testing for an analyte includes a needle (510) for penetrating a patient's skin to access the fluid within the skin. The needle has a hollow body (514) extending from a first end (600) to a second end (601). An interior surface of the body defines a fluid pathway (512) extending between the ends. The second end is positioned to deposit fluid for testing. The first end has a beveled face (520) on a front side of the body. The beveled face terminates at a penetration tip (530) with the beveled face having an opening in communication with the fluid pathway. The penetration tip is burnished to a rounded shape and bent to facilitate low pain and rapid fluid collection.

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav Republic of Macedonia | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | | | TR | Turkey |
| BG | Bulgaria | HU | Hungary | ML | Mali | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MN | Mongolia | UA | Ukraine |
| BR | Brazil | IL | Israel | MR | Mauritania | UG | Uganda |
| BY | Belarus | IS | Iceland | MW | Malawi | US | United States of America |
| CA | Canada | IT | Italy | MX | Mexico | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NE | Niger | VN | Viet Nam |
| CG | Congo | KE | Kenya | NL | Netherlands | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NO | Norway | ZW | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's Republic of Korea | NZ | New Zealand | | |
| CM | Cameroon | | | PL | Poland | | |
| CN | China | KR | Republic of Korea | PT | Portugal | | |
| CU | Cuba | KZ | Kazakstan | RO | Romania | | |
| CZ | Czech Republic | LC | Saint Lucia | RU | Russian Federation | | |
| DE | Germany | LI | Liechtenstein | SD | Sudan | | |
| DK | Denmark | LK | Sri Lanka | SE | Sweden | | |
| EE | Estonia | LR | Liberia | SG | Singapore | | |

# NEEDLE FOR BODY FLUID TESTER

## Technical Field

This invention pertains to testing a body fluid for an analyte. More specifically, the present invention pertains to a novel needle design in combination with a collection apparatus for collecting a sample of such a fluid.

## Background

Numerous patents teach various ways for collecting a sample of body fluid and testing such fluid for an analyte such as glucose. For example, United States Patents 5,820,570 and 5,823,973 describe methods and apparatus for obtaining, in one embodiment, interstitial fluid which is tested for glucose through IR absorption. These patents also describe use of the disclosed inventions in colormetric and electro-chemical testing of glucose.

Present development efforts are directed to testing very small volumes of body fluid (e.g. about 0.5 μl). The use of such small volumes of fluid permits less painful collection of a fluid samples. However, small fluid volumes present additional challenges for analyte testing. For example, testing for analytes typically requires a fluid sample in excess of a predetermined minimum volume. By way of non-limiting representative example, a test may require a minimum sample size of about 1 to 5 μl to yield reliable test results.

The '973 patent shows a small diameter needle (about 28 to 32 gauge or about 0.36 mm to 0.23 mm outside diameter) with a length to penetrate into but not through a dermis to access interstitial fluid contained within the dermis. Preferably, the fluid is blood-free to facilitate subsequent testing of the fluid for analytes such as glucose.

The use of a small needle dimensioned as described in the '973 patent greatly reduces pain. However, pain may occasionally occur. Further, there is a need for a needle design that enhances the rate at which a sample is collected by such a needle.

## SUMMARY

The present invention is directed to an apparatus for collecting a body fluid for testing for an analyte contained within said body fluid. The apparatus comprises a needle for penetrating a patient's skin to access the fluid within said skin. The needle has a hollow body extending from a first end to a second end with a fluid pathway extending between the ends. The second end is positioned to deposit fluid for testing. The first end is configured to penetrate the skin and includes a beveled face on a front side of said body. The beveled face terminates at a penetration tip. The beveled face has an opening in communication with the fluid pathway. The body has a linear axis adjacent the first end. The first end includes a bend formed on the front side of the beveled face to be deflected toward said front side.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevation view of a needle contained in a sampler;

Figure 2 is a side sectional view of a needle positioned relative to an absorbent membrane;

Figure 3 is a side elevation view of a needle being bent;

Figure 4 is a top plan view of a bent needle;

Figure 5 is a view taken along line 5 – 5 of Figure 4;

Figure 5A is an end view of a discharge end of a bent needle;

Figure 5B is a view taken along lines 5B – 5B of Figure 5A and providing an enlarged view of a bent tip of the needle of Figure 5 and showing a preferred embodiment with the tip bent above the needle;

Figure 6 is a side sectional view of a tip of a prior art needle;

Figure 7 is a top plan view of the needle tip shown in Figure 6; and

Figure 8 is a side elevation view of the needle shown in Figures 6 and 7 following dulling of the needle tip;

Figure 9 is a graphical representation of a collection rate as a function of needle tip displacement for a needle such as that shown in Figs. 5A and 5B; and

Figure 10 is a scatter chart of a collection rate as a function of the bend angle of a needle tip for a needle such as that shown in Figs. 5A and 5B.

## DETAILED DESCRIPTION

Various embodiments of the present invention, including a preferred embodiment, will be described in detail with reference to the drawings wherein like reference numerals represent like parts and assemblies throughout the several views. Reference to the described embodiments does not limit the scope of the invention, which is limited only by the scope of the appended claims.

Throughout the following description, an embodiment of the present invention will be described with reference to collecting a sample of interstitial fluid for glucose testing using a narrow needle that penetrates into, but not through, the dermis. Such sample collection is more fully described in commonly assigned United States Patents 5,823,973 and 5,820,570, the disclosures for both of which are hereby incorporated by reference as though set forth in full. While such a use is a preferred embodiment, the present invention is applicable to other fluid collection systems as well as testing for other fluid analytes.

Figure 1 illustrates a fluid sampler 410 such as that shown in Figures 36 – 40 of United States Patent 5,823,973 (the '973 patent), the disclosure of which is hereby incorporated herein by reference. Figure 2 illustrates a membrane and needle assembly such as that shown in Figure 43 of the '973 patent. For ease of illustration, the present invention will be described to a needle alignment such as that shown in the '973 patent with the axis of the needle parallel to the surface of an absorbing membrane. The invention could also be used in other arrangements. For example, the needle axis can be perpendicular to the membrane and fluid can flow through the membrane to an opposite side for colormetric testing.

Referring now to Figures 1 and 2, the sampler 410 has a hollow handle end 409 with an interior 500 to receive a sample end 411. The sample end 411 pivots on a pin 502. The sample end 411 then can pivot between a storage position within the hollow handle end 409 and a deployed position. Figure 1 shows the sample end 411 pivoted into the deployed position.

The sample end 411 is configured to receive samples such as a fluid. An absorbent membrane 504 is carried on the sample end 411. The sample end 411 also includes a hub or ferrule 506 that terminates at a ring end 508. In one possible

embodiment, the ring end may serve as a pressure ring. A needle 510 is held by the ferrule 506. Additionally, the sample end 411 defines a hole 604 (Fig. 2). An absorbent membrane 504 has a target area T and is arranged so that the target area T overlies the hole 604.

As shown in Fig. 3, the needle 510 includes a hollow, straight tubular body 514, a first or penetration end 600, and a discharge end 601 (shown in Figs. 1 and 2). In one embodiment, the needle 510 is a 30 gauge needle, about 0.3 mm in outside diameter, although other needle gauges can be used. In a preferred embodiment, the penetration end 600 protrudes from the ring end 508 of the ferrule by a predetermined distance. The predetermined distance is set so that the first end 600 will penetrate into, but not through, a patient's dermis when the ring 508 is placed against his or her skin.

The discharge end 601 abuts an absorbent membrane 504 mounted on the sample end 411. In this configuration, the longitudinal axis of the needle 510 is perpendicular to the portion of the membrane 504 that forms the target area T. Additionally, the tubular body 514 has an interior surface 511 (Fig. 5) that defines a fluid pathway 512 extending completely through the needle body 514.

In use, the penetration end 600 of the needle 510 is inserted into the patient's dermis. Fluid then flows along the fluid pathway 512 and through the absorbent membrane 504 to the target area T. The absorbent membrane 504 filters out undesirable stray blood cells that may be present in the fluid. The fluid at the target area can then be tested for elements such as glucose.

One possible way to test the fluid is through the use of infrared light. Alternative embodiments include but are not limited to depositing the fluid on a test strip for colormetric testing or on electrodes for electro-chemical testing.

Referring to Figures 4 and 5, the needle 510 has a primary beveled face 520 and tip 530 formed at its penetration end 600. An entrance hole 521 is formed in the beveled face 520 and is in fluid communication with the fluid path 512. The needle 510 also has a front side 522 and an opposite back side 523. The tip 530 of the needle 510 is displaced toward the front side 522 of the needle 510.

Referring to Figure 3, one possible way to form the needle 510 is as follows. The penetration end 600 of the hollow body 514 is ground at an angle to define the

beveled face 520 so that it extends through the body 514 and forms the sharp penetration tip 530. In one possible embodiment, the beveled face is formed at an angle β (about 9°) with respect to a longitudinal axis CL – CL of the needle body 514. The formation of a beveled face 520 results in formation of the entrance hole 521 on beveled face 520. The present invention is shown with a needle having a single grind forming the beveled face. The present invention is also applicable to needles with multiple grinds forming the beveled face.

After providing a needle body 514 with a flat beveled face 520, a fulcrum 700 is placed at a bend location, which is a distance X from the tip 530. In one possible embodiment, the distance X is about 1.2 mm, although other distances can be used. The tip 530 is then urged toward the front side 522 to permanently displace the tip 530 and form a bend angle α. When the tip 530 is displaced, it moves from being aligned with a plane of the back side 523 of the body 514 to a location spaced by a distance Y from the plane of the back side 523. This method creates an arcuate bend which is approximated in the Figures by the bend angle α. In one possible embodiment, the bend angle α is about 27.1°, although other bend angles are possible.

For reasons not fully understood, the use of a displaced tip 530 results in enhanced fluid collection. Possibly, a pocket is formed around the opening 521 to improve fluid flow. Whatever the mechanism, fluid collection is enhanced. Further, the degree of enhancement improves with the amount of deflection Y. The following table illustrates the amount of time required to collect an adequate sample (in the test presumed to be about 0.9 μl of fluid) for an average of needle samples at various tip displacements Y and for a variety of axial locations X (with X and Y as defined with reference to Fig. 3). The amount of time greatly decreases with an increase in Y. In fact, displacement of the tip above the front plane of the needle body has resulted in enhanced collection. In the following table, negative values of α and Y reflect a backward bending of the tip behind the rear side of the needle. Zero values reflect an unbent needle.

**TABLE A: Time to Collect Pre-determined Amount of Sample**

| Location X (mm) | Angle α (degrees) | Displacement Y (mm) | Time to Collect .9 μl of Sample (seconds) |
|---|---|---|---|
| 1.07 | -6.03 | -0.14 | 26.75 |
| 0 | 0 | 0 | 15.51 |
| 0.88 | 3.24 | 0.09 | 12.75 |
| 1.57 | 5.71 | 0.13 | 10.41 |
| 0.86 | 11.3 | 0.15 | 11.46 |
| 2.03 | 8.13 | 0.25 | 12.74 |
| 1.30 | 12.8 | 0.279 | 9.04 |
| 0.59 | 28.3 | 0.281 | 7.63 |
| 1.68 | 13.7 | 0.38 | 7.96 |
| 0.94 | 25.9 | 0.43 | 6.62 |
| 1.41 | 21.6 | 0.51 | 5.66 |

Figures 5A and 5B illustrate a preferred embodiment where the tip 530" is displaced above the front side 522" of the needle 510". In Figs. 5A and 5B, elements in common with those of the embodiment of Figs. 3 – 5 are similarly numbered (and need not be separately discussed beyond what follows) with the addition of a double apostrophe to distinguish the embodiments.

The needle 510" is .012 inch (about .3048 mm or 30 gauge) outside diameter. The preferred embodiment was derived following experimentation subsequent to that enumerated in the above table. In Figure 5B, the bend angle θ is the lesser included angle of a straight line A tangent to the bent portion 600" and an extension line B of the straight portion. The distance Y is the distance between the tip 530" and the straight line extension B. The distance X is the distance from the intersection of the tangent line A and straight line extension B to the tip 530". All of the data in the following table illustrate fluid collection rate (measured in micro-liters per second, μl/sec.) as measured using a preferred value of X equal to .035 inch (about .8890 mm). The negative values for θ and Y represent a downward bend. Positive values represent upward bends as illustrated in Figure 5B. A zero value represents an unbent needle.

**TABLE B: Fluid Collection Rate (Micro-Liters/Second)**

| | VALUES of Y | | | | | |
|---|---|---|---|---|---|---|
| Bend Angle (θ) in degrees | -.006 inch (≅ -.1524 mm) | .000 inch (≅ .0000 mm) | .005 inch (≅ .1270 mm) | .012 inch (≅ .3048 mm) | .016 inch (≅ .4064 mm) | .020 inch (≅ .5080 mm) |
| -8.1 | 0.06 | | | | | |
| 0.0 | | 0.10 | | | | |
| 4.6 | | | 0.13 | | | |
| 6.5 | | | 0.13 | | | |
| 7.1 | | | | 0.12 | | |
| 7.6 | | | 0.10 | | | |
| 10.0 | | | 0.14 | | | |
| 12.2 | | | | 0.15 | | |
| 12.2 | | | | 0.13 | | |
| 12.8 | | | | | 0.16 | |
| 14.9 | | | | 0.13 | | |
| 16.8 | | | | 0.13 | | |
| 20.0 | | | | | | 0.19 |
| 21.6 | | | | | | 0.17 |
| 21.8 | | | | 0.16 | | |
| 24.7 | | | | | 0.19 | |
| 25.6 | | | | 0.18 | | |
| 26.6 | | | | 0.15 | | |
| 31.2 | | | | | | 0.20 |
| 46.4 | | | | | | 0.20 |

Using the above data, Figure 9 is a graphical representation of the collection rate (μl/sec.) as a function of the Y displacement (where Y is the average Y values for various angles from the data in Fig. θ). Figure 10 is a scatter chart of the data plotted as collection rate (μl/sec.) as a function of the bend angle θ.

The above data show for a small gauge needle, collection rate improves with increases in both the bend angle θ and the displacement Y. In fact, displacements greater than the needle's outside diameter of .012 inch (representing a bending of the tip 530" above the front side 522" of the needle 510") shows improved collection rates.

Since pain avoidance is a desirable feature, patients selected to collect the above data were asked to compare pain sensation using the above-configured needles. While pain is subjective, it was surprising to note the patient population did

not record appreciable increase in pain until the bend angle θ exceeded 30°-- 40°. The data suggest optimum design of a low pain needle for maximizing fluid collection rates is to provide a bend angle θ of about 30° and preferably between 20° and 40° with the tip 530" of the needle bent above the plane of the needle 510".

In certain applications (for example, collecting interstitial fluid for testing), it is desirable for the fluid to have a low blood content so as to be substantially blood-free. By substantially blood free, it is meant a sample with a hemocrit content of less than 10%. Using the bent needle 510" as described, the frequency of occurrence of blood in a sample increases compared to a straight needle, but the samples continue to be substantially blood free. The present needle 510" can also be used to collect higher blood content samples. In both, the design as described increases flow rate while retaining a low pain quality.

In addition to the bend angle described above, the needle 510 is dulled at the penetration end. The dulled edges at the penetration end have benefits separate from the displaced tip described above. Specifically, the dulled edges are found to reduce the amount of unwanted blood in a collected sample of interstitial fluid.

Figures 6-8, illustrate a needle having a straight tip before and after its edges are dulled. Although the dulled edges are illustrated on a needle having a straight tip, they also could be used in conjunction with a displaced tip as described above. Elements and structures that are in common with the embodiments described above are marked with the same reference numerals with the addition of an apostrophe.

Referring now to Figures 6 and 7, the beveled face 520' is initially formed by grinding the needle 514' at the penetration end 600' as discussed above to form opening 521' (shown in Fig. 7). This grinding forms an outer peripheral edge 630', which is defined by the intersection of the beveled face 520' and the outer surface of the cylindrical body 514'. Additionally, an inner peripheral edge 632' is defined by the intersection of the beveled face 520' and the interior surface 511' of the needle body 514'. Upon grinding the needle to form the beveled face 520', the inner and outer peripheral edges 630' and 632' and tip 530' are initially sharp (i.e., are formed at substantially non-rounded intersections).

After the beveled face 520' is formed, the inner and outer edges 630' and 632' and tip 530' are dulled so that they become burnished or radiused. The dulled

edges are formed in a burnishing operation by tumbling the needle 510' in a tumbler with a polishing medium. In one possible embodiment, the polishing medium is a fine media such as 1 mm ceramic spheres and a soap solution. About 5,000 needles are tumbled in a single batch in the polishing medium for about 20 minutes. Other possible tumbling methods use a different polishing medium, different batch sizes, or different lengths of time.

Referring to Figure 8, this process dulls the inner and outer edges 630' and 632' and tip 530'. In one possible embodiment, the edges 630' and 632' and tip 530' are dulled to a radius of about 0.002 inch or about 0.05 mm. Although a burnishing process is described herein, manufacturing processes other than tumbling may be used to form the dulled edges.

From the foregoing detailed description, the present invention has been described in a preferred embodiment. Modifications and equivalents of such disclosure are intended to be included in the appended claims. For example, the benefits of the displaced tip can be attained without the dulled edges of the needle. Similarly, the benefits of the dulled edges can be attained without the displaced tip of the needle. Additionally, all needles have been shown with a single bevel. Nevertheless, the present invention is applicable to a needle with multiple bevels.

The claimed invention is:

1 An apparatus for collecting a body fluid for testing for an analyte contained within said body fluid, said apparatus comprising:

a needle for penetrating a patient's skin to access said fluid within said skin;

said needle having a hollow body extending from a first end to a second end with a fluid pathway extending between said ends;

said second end positioned to deposit fluid for subsequent testing;

said first end configured to penetrate said skin and including a beveled face on a front side of said body with said beveled face terminating at a penetration tip with said beveled face having an opening in communication with said fluid pathway;

said body having a linear axis adjacent said first end; and

said first end including a bend formed on said front side for at least a forward portion of said beveled face to be deflected toward said front side with said tip disposed above said axis.

2. An apparatus according to claim 1 wherein said bend is positioned on said beveled face.

3. An apparatus according to claim 1 wherein said beveled face is deflected for said penetration tip to be positioned protruding beyond a plane of said body at said front side.

4. An apparatus according to claim 1 wherein:

said beveled face extends through a transverse dimension of said body for said penetration tip to define a point on a back side of said body;

said bend positioned at a location on said beveled face for said tip to be displaced from said back side and toward said front side.

5. An apparatus according to claim 4 wherein said body is substantially tubular and said beveled face is a flat surface at an angle to said body prior to said bend.

6. An apparatus according to claim 1 wherein an interior surface of said body defines said fluid pathway, said apparatus further comprising:

said beveled face intersecting with an exterior surface of said body to define an outer peripheral edge and said beveled face intersecting with said interior surface to define an inner peripheral edge defining said opening;

said outer peripheral edge shaped to present a rounded edge.

7. An apparatus according to claim 6 wherein said inner peripheral edge is shaped to present a rounded edge.

8. An apparatus according to claim 1 wherein the needle is restrained for the tip to penetrate into and not through the dermis.

9. An apparatus according to claim 1 wherein said first end is set at an angle to said axis between about 20° and 40°.

10. An apparatus according to claim 1 wherein said first end is set at an angle to said axis of about 30°.

11. A method for collecting a sample of body fluid from a skin layer of a patient, said method comprising:

selecting a needle having a hollow body extending from a first end to a second end with a fluid pathway extending between said ends, said second end positioned to deposit fluid for testing, said first end configured to penetrate said skin and including a beveled face on a front side of said body with said beveled face terminating at a penetration tip with said beveled face having an opening in communication with said fluid pathway, said body having a linear axis adjacent said first end, and said first end including a bend formed on said front side for at least a forward portion of said beveled face to

be deflected toward said front side and with said tip disposed above said axis; and

penetrating said tip into said skin layer to collect said body fluid in said needle.

5

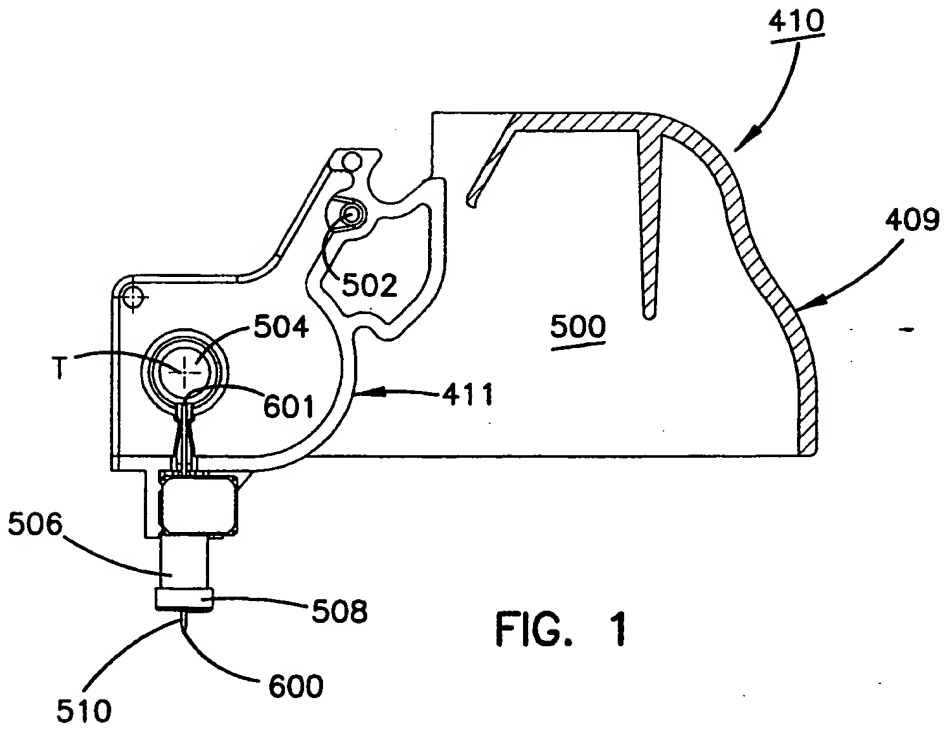

410
409
502
504
500
T
601
411
506
508
510
600

FIG. 1

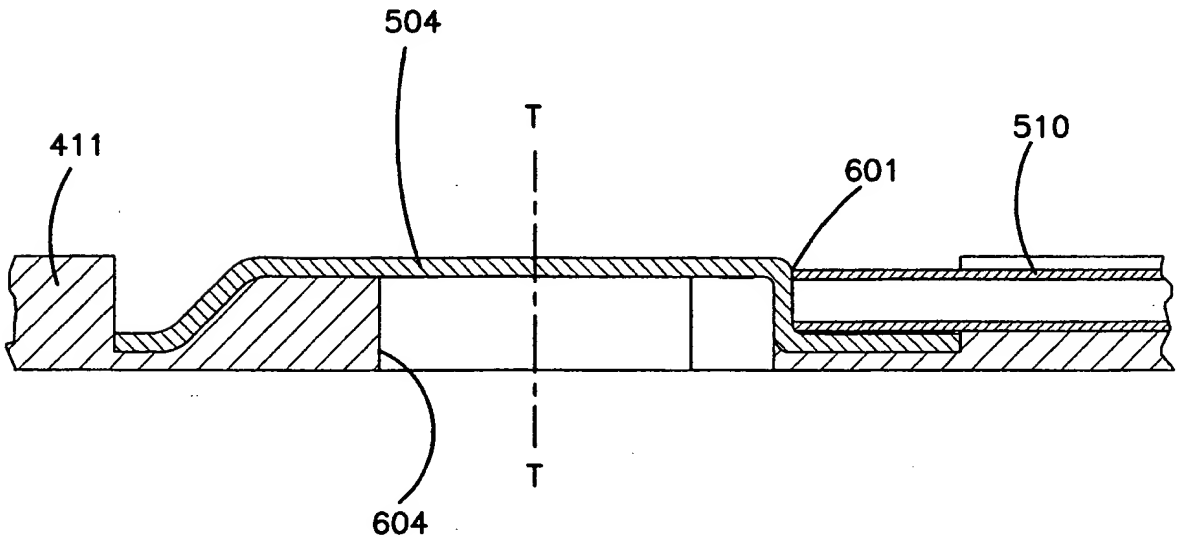

504
T
411
601
510
T
604

FIG. 2

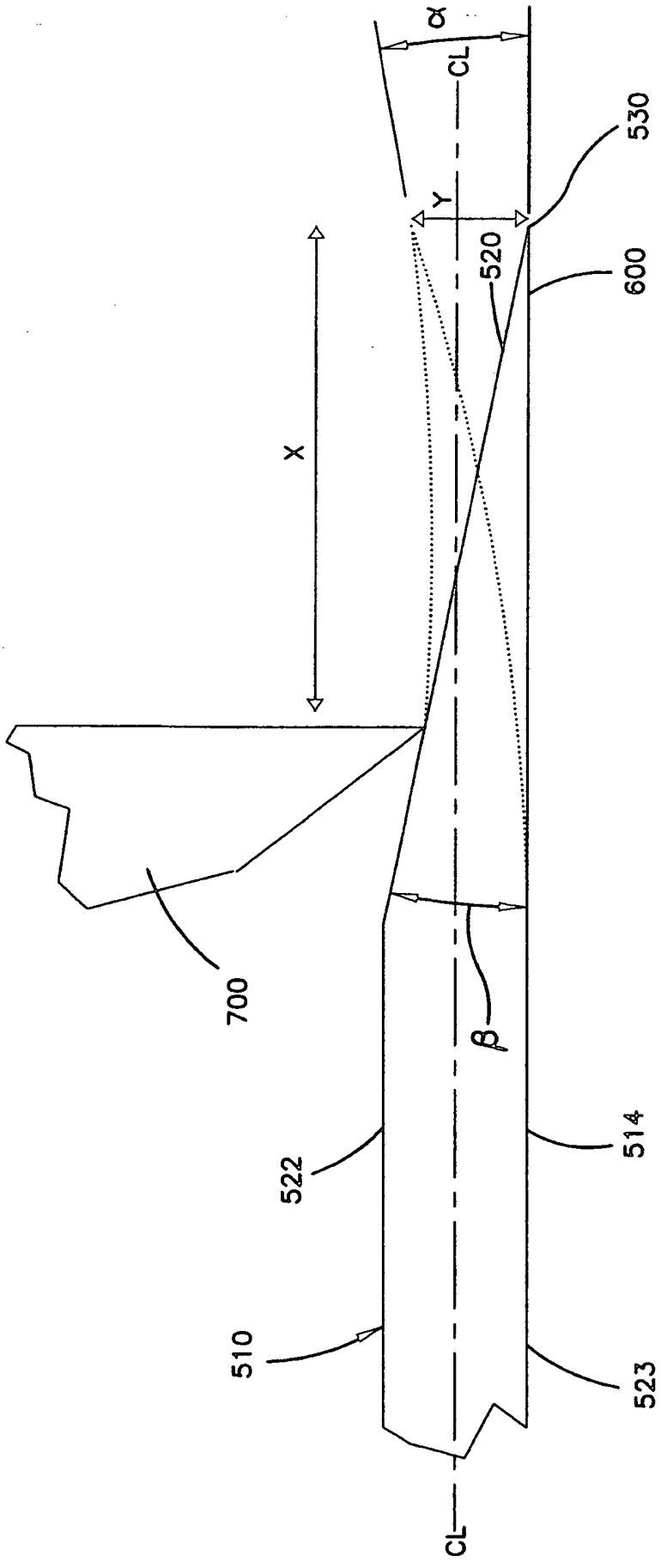



FIG. 3

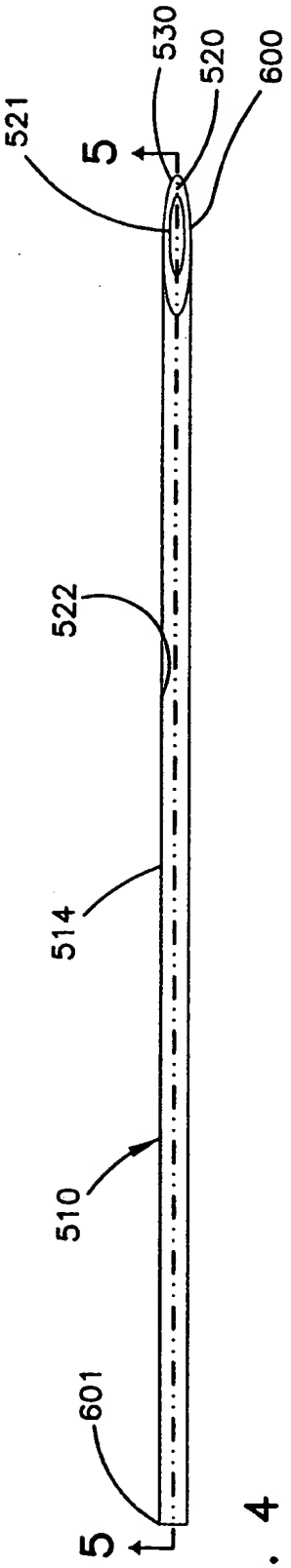

530
520
600
521
5
522
514
510
601
5

FIG. 4

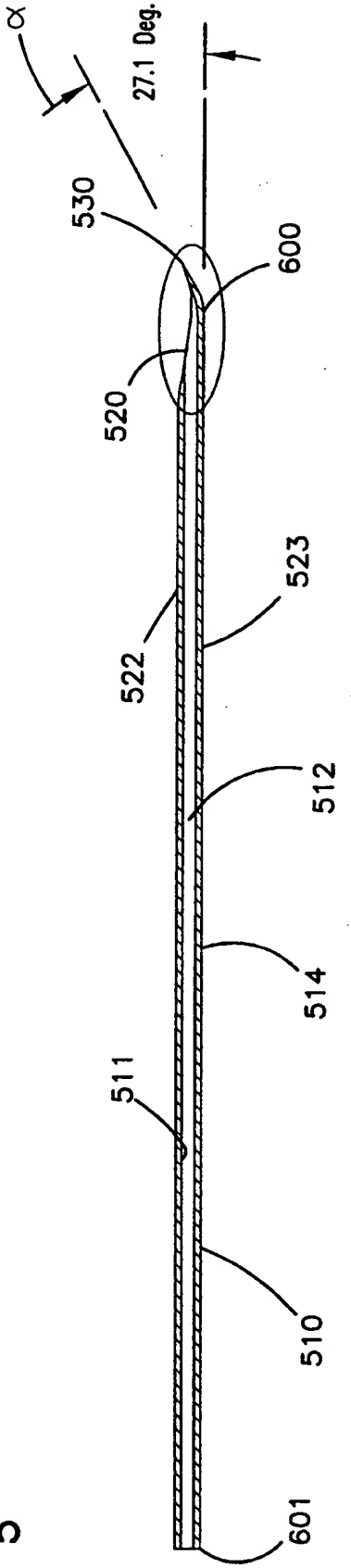

α
27.1 Deg.
530
600
520
523
522
512
514
511
510
601

FIG. 5

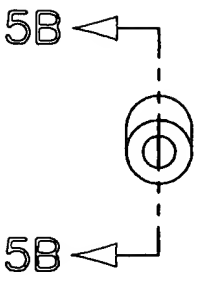



FIG. 5A

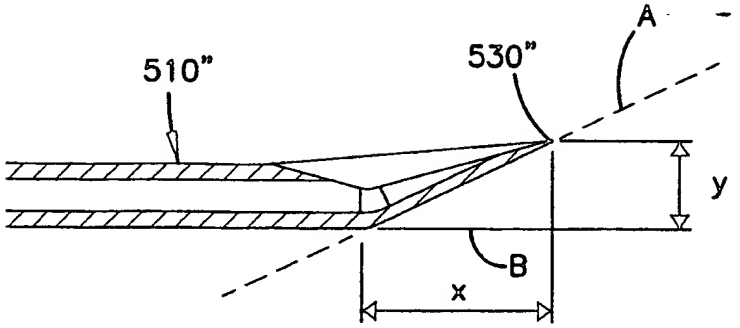



FIG. 5B

FIG. 6

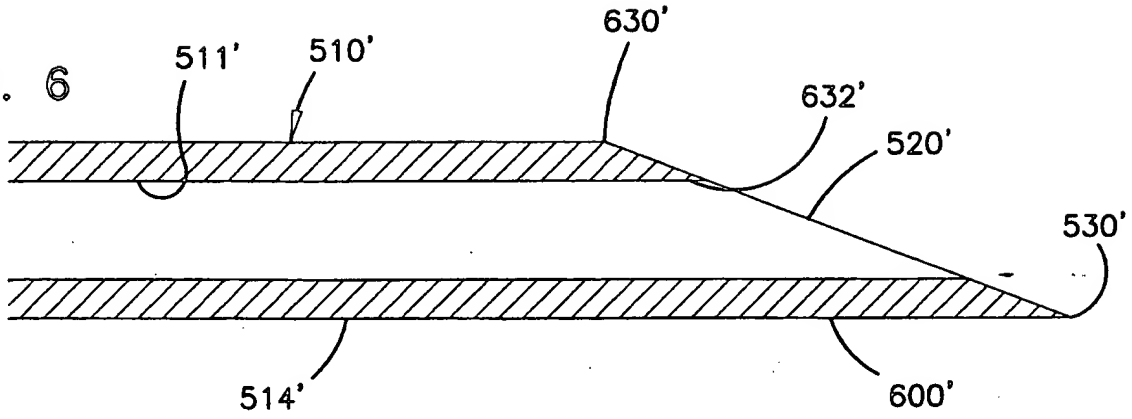



FIG. 7

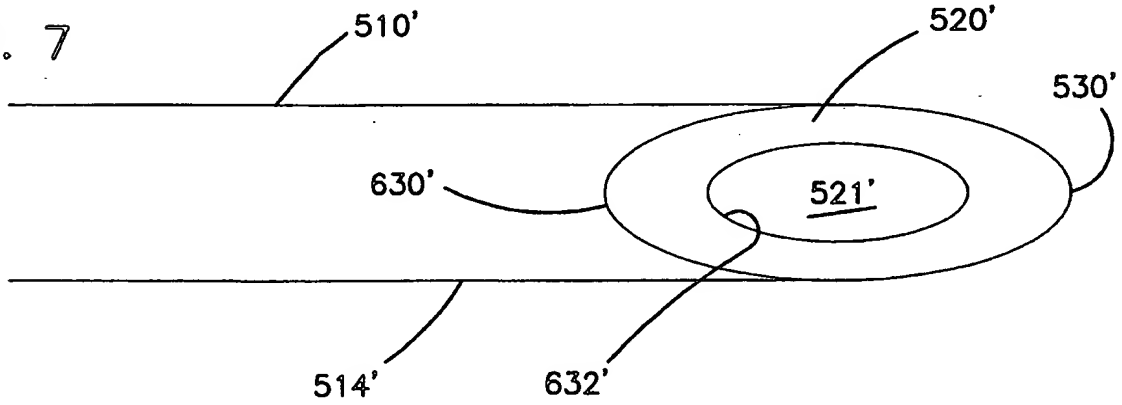
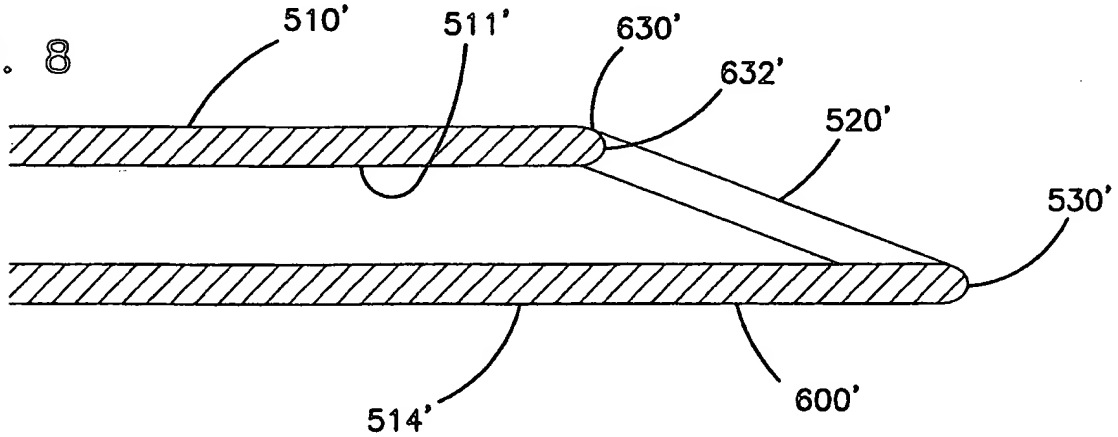



FIG. 8



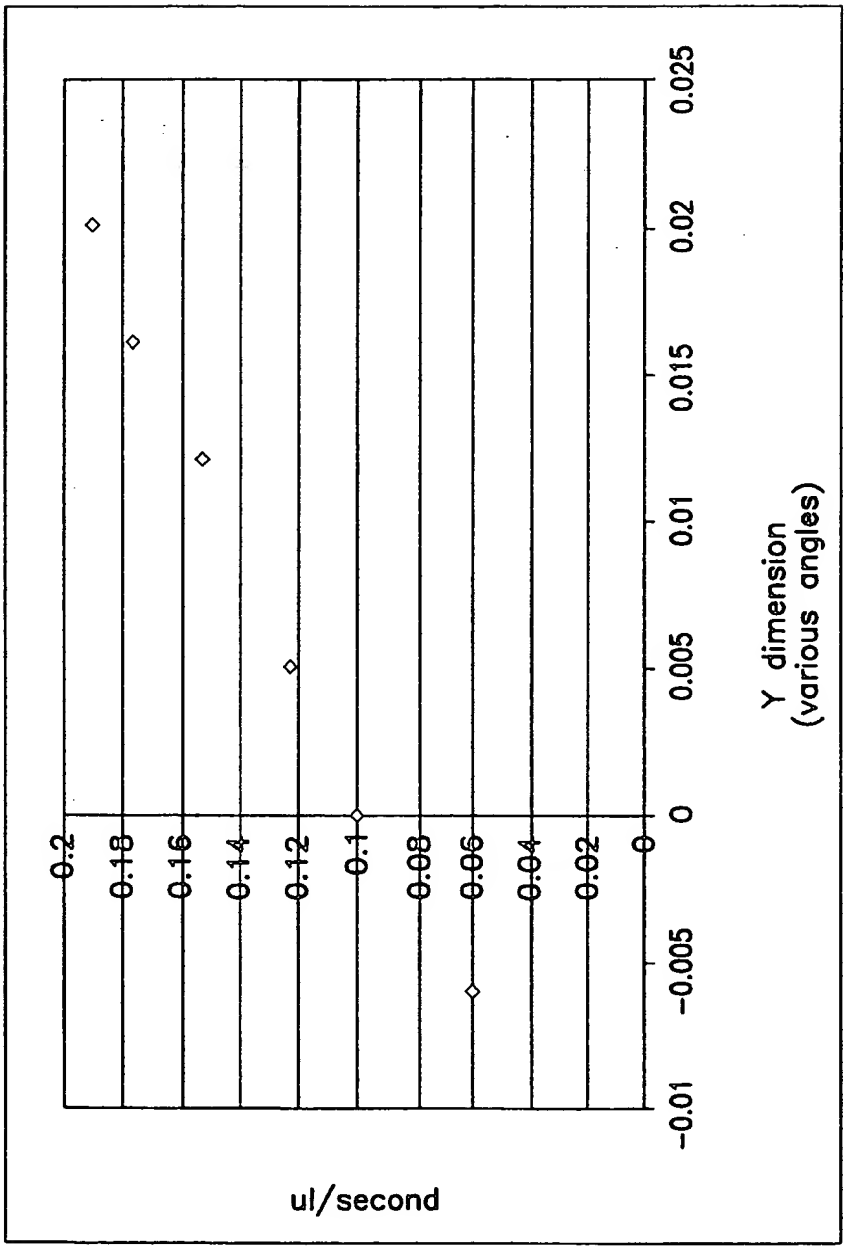

0.2
0.18
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
-0.01
-0.005
0
0.005
0.01
0.015
0.02
0.025
ul/second
Y dimension
(various angles)
Y dimension Mean rate (ul/sec)
-0.006 0.060
0.000 0.100
0.005 0.123
0.012 0.152
0.016 0.176
0.020 0.190

FIG. 9

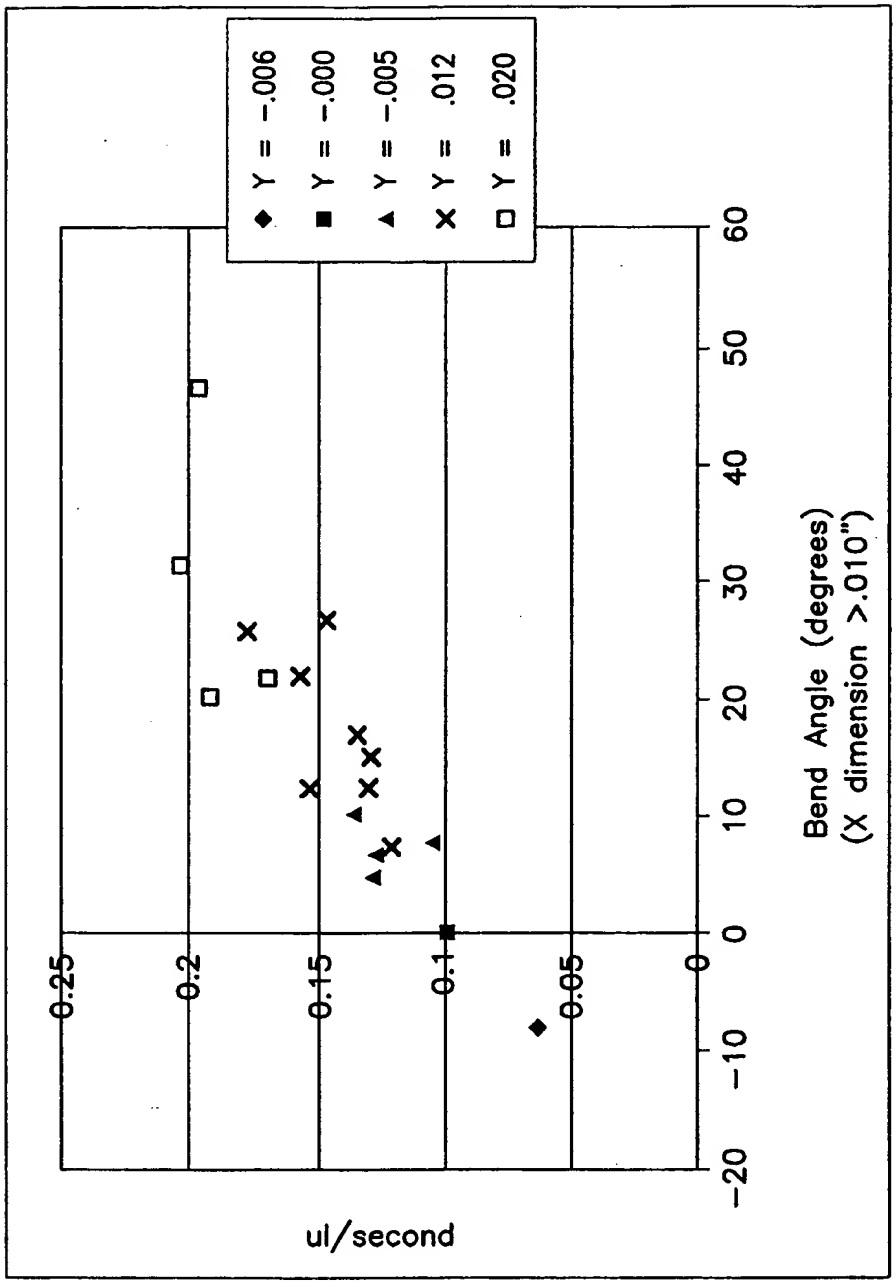

Y = -.006
Y = -.000
Y = -.005
Y = .012
Y = .020
0.25
0.2
0.15
0.1
0.05
0
ul/second
60
50
40
30
20
10
0
-10
-20
Bend Angle (degrees)
(X dimension >.010")

FIG. 10

# INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 00/02086

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ' | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 5 823 973 A ( J. R. RACCHINI ET AL ) 20 October 1998 (1998-10-20) cited in the application | 1,11 |
| A | column 1, line 34 -column 2, line 14 | 2-8 |
| Y | WO 82 02678 A ( AMERICAN HOSPITAL SUPPLY CORPORATION ) 19 August 1982 (1982-08-19) | 1,11 |
| A | page 3, line 8 -page 5, line 18 | 4-8 |
| Y | EP 0 872 215 A (BECTON, DICKINSON AND CO.) 21 October 1998 (1998-10-21) | 1,11 |
| A | page 4, line 11 - line 45 | 9,10 |
| A | US 4 518 383 A ( J. M. EVANS ) 21 May 1985 (1985-05-21) column 1, line 50 -column 2, line 9 | 1,11 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

' Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 30 June 2000 | 07/07/2000 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office. P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040. Tx. 31 651 epo nl.<br>Fax: (+31-70) 340-3016 | Geffen, N |

1

Form PCT/ISA/210 (second sheet) (July 1992)

**The claimed invention is:**

1 An apparatus for collecting a body fluid for testing for an analyte contained within said body fluid, said apparatus comprising:

a needle for penetrating a patient's skin to access said fluid within said skin;

said needle having a hollow body extending from a first end to a second end with a fluid pathway extending between said ends;

said second end positioned to deposit fluid for subsequent testing;

said first end configured to penetrate said skin and including a beveled face on a front side of said body with said beveled face terminating at a penetration tip with said beveled face having an opening in communication with said fluid pathway;

said body having a linear axis adjacent said first end; and

said first end including a bend formed on said front side for at least a forward portion of said beveled face to be deflected toward said front side with said tip disposed above said axis.

2. An apparatus according to claim 1 wherein said bend is positioned on said beveled face.

3. An apparatus according to claim 1 wherein said beveled face is deflected for said penetration tip to be positioned protruding beyond a plane of said body at said front side.

4. An apparatus according to claim 1 wherein:

said beveled face extends through a transverse dimension of said body for said penetration tip to define a point on a back side of said body;

said bend positioned at a location on said beveled face for said tip to be displaced from said back side and toward said front side.

5. An apparatus according to claim 4 wherein said body is substantially tubular and said beveled face is a flat surface at an angle to said body prior to said bend.